Maryland Board of Pharmacy Public Meeting Minutes

Date: April 20, 2011

Name	Title	Present	Absent	Present	Absent
Bradley-Baker, L.	Commissioner	X		8	2
Chason, D.	Commissioner	Х		9	1
Finke, H.	Commissioner	Х		10	0
Gavgani, M. Z.	Commissioner	Х		7	1
Handelman, M.	Commissioner		Х	8	2
Israbian-Jamgochian, L.	Commissioner/Treasurer	Х		10	0
Matens, R.	Commissioner	Х		10	0
Souranis, M.	Commissioner//President	Х		10	0
St. Cyr, II, Z. W.	Commissioner	X		8	2
Taylor, D.	Commissioner	X		9	1
Taylor, R.	Commissioner/Secretary	X		9	1
Zimmer, R.	Commissioner	X		9	1
Bethman, L.	Board Counsel	Х		10	0
Banks, T.	MIS Manager	х		10	0
Wu, YuZon	Compliance Manager	Х		3	0
Daniels, Demetrius	Licensing Manager	Х		10	0
Gaither, P.	Administration and Public Support Manager		Х	9	1
Jeffers, A.	Legislation/Regulations Manager	Х		9	1
Naesea, L.	Executive Director	Х		10	0

Subject	Responsible		Action Due Date	Board
	Party	Discussion	(Assigned To)	Action
I. Executive	A. M.	Members of the Board with a conflict of interest relating to		
Committee Report(s)	Souranis,	the agenda are advised to notify the Board at this time	or when the	
	Board President	issue is addressed in the agenda.		
		1. M. Souranis called the Public Meeting to order at §	9:41 A.M.	
		2. M. Souranis requested all meeting attendees to in themselves and to remember to sign the guest list		
		leaving the meeting. M. Souranis asked guests to		
		sign-in sheet if they were requesting CE Units for		
		 M. Souranis reported that guests will be given page materials so that they can follow meeting discuss requested that all guests return their draft packets leave the meeting. 	ions. He	
		4. Review & Approval of Minutes of March 16, 2011.	Motion: to accept minutes as amended	Board Action: The Board
		Page 1, Section I, change guest to guests in numb		voted to
		Page 2, Section II, number 2 change defend to opp	oosed Motion: L Israbian-	approve
		Page 40, Section III D change cashes to caches	Jamgochian	
			Seconded: R. Zimmer	Board Action: The Board
			Motion: minutes as	voted to
			amended	approve

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II. Staff Operations Report (s)	A. L. Naesea, Executive Director	1 Operations Updates: L. Naesea reported on behalf of P. Gaither that the Board is nearly at full staff except for two and a half vacancies. A. Jeffers and L. Naesea have completed interviews for the Board Secretary and have a potential selection. The Board is still awaiting a response to it freeze exempt request to recruit for the Office Secretary II position in the Compliance Unit. The Board is appealing the denial of its request to fill the Pharmacist II 50 % position. 2. Meeting Updates: M. Souranis attended the APCE evaluation process on the Eastern Shore. The University of Maryland Eastern Shore School of Pharmacy is seeking accreditation of its proposed pharmacy school curriculum. Mr. Souranis indicated that the he school is on the right track and is needed on the Eastern shore. The ACPE survey shows that the school is making progress in meeting all requirements. L. Naesea reported on the following: The NABP meeting will be next		
		month and L. Israbian-Jamgochian will be attending as the Board delegate. In June all Board administrators will be meeting with Secretary Dr. Joshua Sharfstein.		
	B. P. Gaither, APS Manager	Excused Absence		
	C. D. Daniels, Licensing Manager	The Board had a total of 18,599 licensees for the month of March, including: 8745 pharmacists, 1,742 pharmacies, 685 distributors and 7,427 technicians.		
	D. T. Banks, MIS Manager	The Board is on schedule with programming for the database project. There have been delays in receiving delivery of ordered hardware however; the contractors are continuing to work on content development until the hardware arrives. The entire licensing component is completed and template development is in progress. The Board's proposed		

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		automated licensing and front desk processes were approved by the		
		Department's internal auditors.		
	E. Y. Wu, Compliance Manager	Inspection Program Report - A total of 141 inspections were completed in March of which: 111 were annual pharmacy inspections, 13 were pharmacy openings, 13 were pharmacy relocations, and 4 others related to investigation.		
		2. Compliance Unit Updates - The Board received 28 complaints in the month of March.		
		3. PEAC Update – Tony Tommasello reported that PEAC support 18 cases in March of which one was new. There were two positive drug tests results for one pharmacist; however, the pharmacist was undergoing surgery and the positives were related to that procedure.		
	F. A. Jeffers,Legs & Regs Manager	Status of Proposed Regulations a. 10.34.03 Inpatient Institutional Pharmacy Re-submitted for publication on January 31, 2011. Anticipated to be published June 3, 2011 through July 5, 2011.		
		b. 10.34.23 Pharmaceutical Services to Patients in Comprehensive Care Facilities		
		Published in the Maryland Register January 3, 2011.		
		Notice of Final Action submitted March 21, 2011. Anticipated to be published		
		May 6 th or May 20 th , 2011.		
		c. 10.34.25 Delivery of Prescriptions		
		Submitted for publication on August 4, 2010.		
		d. 10.34.28 Automated Medication Systems		
			2d- Motion: to approve	2d-Board

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		Re-proposal published in the Maryland Register January 14, 2011. Comments to be received through February 14, 2011. One comment received from Kaiser Permanente. COMAR 10.34.28 automated medication systems Kaiser Perman	response to Kaiser Permanente Comment. Seconded: R.Matens	Action: The Board voted to approve motion
		DRAFT II - Board Response - Comment on reproposal 10.34.28 KP 040411	Motion: to approve Board response Seconded: R. Zimmer	
		Thank you for commenting to the Maryland Board of Pharmacy (the "Board") concerning the proposed Code of Maryland Regulations (COMAR)10.34.28 Automated Medication Systems, as published in 36:25 Md. R. 1965 – 1969 (December 4, 2009) and the re-proposal published in 38:2 Md. R. 93 - 94 (January 14, 2011). Below you will find the Board's responses to Kaiser Permanente's concerns.		
		.01 Definitions Kaiser Permanente requested that "or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, § 19-713.6, Annotated Code of Maryland" be added to the definitions of automated medication system; decentralized automated medication system; and remote automated medication system.		
		The Board agrees and will withdraw the existing proposal and re-proposal and make the additions to the definitions in a new proposal.		
		Additionally, if "group model health maintenance organizations" are added to "remote automated medication system" then Kaiser Permanente would have to adhere to the same standards as all pharmacies with a remote automated medication system. Remote automated medication systems are intended for a doctor or nurse to remove the medications from the system for "administration" to a patient. A "remote" system is not intended for retail dispensing. A "remote" system is intended only to be used to distribute medications for administration purposes.		
		Upon review, the Board will be revising the definitions, and usage requirements, for "remote automated medication system" and "decentralized automated medication system" to restrict the use of these systems for distribution only.		

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		Finally, the Board will be further revising the definition for "remote automated medications system" by adding a subparagraph (vi) "Is stocked and controlled by a pharmacy providing services to the facility."		
		The definitions to be proposed this spring in 10.34.28.02B follow:		
		.02 Definitions.		
		(1) "Automated medication system" means a <u>centralized</u> , <u>decentralized</u> , <u>or</u> <u>remote</u> robotic or computerized device and that device's components designed to:		
		(a) Distribute medications in a licensed health care facility, related institution, as defined in Health-General Article, § 19-301, Annotated Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, § 19-713.6, Annotated Code of Maryland; or		
		(b) Prepare medications for final dispensing by a licensed pharmacist [to a patient or a patient's agent].		
		(3) "Decentralized automated medication system" means an automated medication system that is located outside of the pharmacy in a health care facility, related institution, as defined in Health-General Article, § 19-301, Annotated Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, § 19-713.6, Annotated Code of Maryland, with an on-site pharmacy and in which medication is stored in a manner that may be, but need not be, patient specific.		
		(5) Remote Automated Medication System.		
		(a) "Remote Automated Medication System" means an automated medication system that is located in a health care facility, related institution, as defined in Health-General Article, § 19-301, Annotated Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, § 19-713.6, Annotated Code of Maryland, that does not have an on-site pharmacy and in which medication is stored in a manner that may be, but need not be, patient specific.		
		(b) "Remote automated medication system" does not include an interim box		

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		or other similar medication storage container that:		
		(i) Does not operate pursuant to the entry of a medication order;		
		(ii) Does not require a pharmacist's review before access to medication;		
		(iii) Is stocked with unit dose medications;		
		(iv) Has the sole purpose of providing a medication dosage pending the next pharmacy delivery to the facility:		
		(v) Is located in a patient care setting that does not have a pharmacy on site; and		
		(vi) Is stocked and controlled by a pharmacy providing services to the facility.		
		The additional usage requirements to be proposed this spring follow:		
		.05 Usage Requirements for Decentralized Automated Medication Systems.		
		A. A decentralized automated medication system may only be used if:		
		(5) It is designed to distribute medications in a licensed health care facility, related institution, as defined in Health-General Article, § 19-301, Annotated Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, § 19-713.6, Annotated Code of Maryland.		
		.06 Usage Requirements for Remote Automated Medication Systems.		
		A. A remote automated medication system may only be used if:		
		(5) It is designed to distribute medications in a licensed health care facility, related institution, as defined in Health-General Article, § 19-301, Annotated Code of Maryland, or a medical facility owned and operated by a group model health maintenance organization as defined in Health-General Article, § 19-713.6, Annotated Code of Maryland.		
		.05 Usage Requirements for Decentralized Automated Medication		

Party	Systems: .06 Usage Requirements for Remote Automated Medication Systems. As you indicated in your letter to the Board, Regulations .05 and .06, related to decentralized and remote automated medications systems, require that a licensed pharmacist review each order for medication (a) after the order has been entered into the system; and (b) before the system permits access to the medication. An exception is made in both regulations for "starter doses" which are administered by health care professionals who are legally authorized to do so. For starter doses, or in response to an emergency, the pharmacist has 24 hours to review the order authorizing removal of the medication from the system. You had asked that the Board not require pharmacist review of medications removed from the system by a licensed health care professional.	(Assigned To)	
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	* *		
	health care professional.		
	You had mentioned that the key in these regulations is that drugs are not		
	being dispensed, but rather administered by licensed heath care professionals		
	legally authorized to do so. The issue is not that the drugs are not dispensed,		
	but rather that they are distributed from the pharmacy through the automated		
	system and then to the health care professional. See the definition of		
	"Distribute" in Health Occupations Article, 12-101(i), Annotated Code of		
	Maryland. A review of an order authorizing the distribution of medications by		
	a pharmacist ensures that patients have prompt access to pharmacy services		
	necessary for the provision of good pharmaceutical care.		
	.08 Return of Unused Medication.		
	The Board will not reconsider its position regarding returning unused		
	medications to a centralized automated medication system. It is the standard		
	of practice not to return unused medications into an automated medication		
	system or a stock bottle.		
	The Board would like to thank you again for your thorough reading of, and		
	comments to, the proposed and re-proposed COMAR 10.34.28 Automated	Motion: to approve	
	Medication Systems. The Board considered your comments at the April 20,	revisions to COMAR	
	2011 Board Meeting and voted to withdraw the proposal and re-proposal and	10.34.28 .	
	submit a new proposal for COMAR 10.34.28 to reflect the substantive	Seconded: R.Matens	Board Action:
	changes outlined above.		The Board
	New proposal approved by the Board with revisions pursuant to the		voted to
	Board's response to Kaiser Permanente		approve motion
	proposed-7-10 COMAR 10.34.28 Auto Med Systems		

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		40.04.05 Harris Infrasion Pharmacon Compiler		
		e. 10.34.35 Home Infusion Pharmacy Services		
		Final version approved at February 16, 2011 Board Meeting. To be		
		submitted as soon as possible		
		f. 10.13.01 Dispensing of Prescription Drugs by a Licensee		
		A meeting was held with representatives from the stakeholder Boards per direction from Wendy Kronmiller on September 30, 2010. Wendy will schedule another meeting in the future.		
		DDC PIA request for Inspection Reports – DDC requested an extension until		
		December 17 th – Received December 16, 2010. Database of information		
		created.		
		Legislation was introduced but did not pass.		
		Anna Jeffers will follow up with Sara Fidler,Counsel to the Senate Education,		
		Health and Environmental Affairs Committee concerning the upcoming Health		
		Subcommittee's assistance in resolving the dispensing of prescription drugs		
		by licensees.		
		Regulatory Proposal on a related matter:		
		14.09.03 012811 publication - WCC - fees		
		14.09.03 Notice of Hearing		
		Report on hearing held April 14, 2011.		
		Anna Jeffers reported on the hearing for COMAR 14.09.03 Guide of		
		Medical and Surgical Fees, Workers' Compensation		
		Commission. A summary of the testimony of several witnesses		

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		follows:		
		NCCI - National Council on Compensation Insurance - Laurie Lovegrin		
		- Supports the regulations - would create a 2.4% savings		
		Supports the regulations - would create a 2.170 savings		
		Property Casualty Ins. Co. of America - Bob Enten - Supports the		
		regulations - Lowers rates and saves money. Not an inconvenience for		
		physicians and easy to implement		
		<u>Industrial Pharmacy Management</u> - Chris Van Ruso and Mike Drobot -		
		Opposed - He believes the formula would be the lowest in the country		
		and unreasonable. He would prefer a phase-in of the lower rates over		
		time. They also do not support eliminating physician dispensing. He		
		believes that the Commission's facts utilized to revise the regulations		
		are "outlyers."		
		are outiyers.		
		<u>Injured Workers's Pharmacy</u> - Mike Asickis - Also supports a gradual		
		lowering of rates.		
		American Ins. Association - Jack Andersack - He would like the		
		regulations revised with his submitted amendments. He did not		
		discuss at the hearing what those amendments were. He believes the		
		regulations address a serious cost driver.		
		MedChi & Auto Health Care Solutions - Jay Schwartz - He maintains		
		that it would be less expensive for the patients to receive their		
		medications from physicians. He thinks that injured workers should be		
		encouraged to obtain their prescriptions from physicians. He believes		
		making the patient go to a pharmacy penalizes them. He indicated		
		that the physicians pay more for the prepackaged medications		
		because they do not buy in bulk like the pharmacies. He said there is		
		no data to support that physicians only have certain drugs.		
		no data to support that physicians only have certain drugs.		
		Spine Center - Dr. Mark Love - He is interested in fair and reasonable		
		pricing. He Workers' Comp Patients are 13% of his practice. He		
		maintained that dispensing by the physician leads to over all less		
		expensive care. He spoke of the benefits of the physician dispensing		
	<u> </u>	Q		1

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		and reassessing patients on a regular basis. He mentioned		
		transportation being an issued for some patients to get to a		
		pharmacy. He prefers to dispense less medication than a pharmacy		
		would so he can keep track of his patient's progress.		
		<u>Laurie Robinson</u> , patient - she said mail order missed deliveries and		
		pharmacies do not always carry the drugs she needs. She prefers		
		getting her drugs from the Spine Center.		
		<u>Dr. Ross Sugar</u> -pain physician - He believes outcomes are improved		
		with physician dispensing. He was nervous about meeting costs if the		
		rate was lowered.		
		<u>Dr. Zimmerman</u> - a surgeon with experience with Workers' Comp. He		
		says that when patients go to the pharmacy there are problems		
		obtaining medications because they often do not have their Workers'		
		Comp cards with them. He said that sometimes claimants pay out of		
		pocket because of complications at the pharmacy. He also said that		
		pharmacies only give brand names instead of generic. He said that		
		costs go up because patients have their claims denied and then have		
		to hire a lawyer. He said that once conflict occurs and access to drugs		
		is denied, it leads to longer care.		
		Anna Jeffers will follow up with the WCC concerning the next steps in the development of these regulations.	2. Motion: Practice Committee made a motion to ratify letters as a group	
		2. Legislation - Letters and Position Papers for Ratification:	Seconded : D. Taylor	Board Action: The Board
		a. SB 845 Health Occupations – Pharmacists – Adminsitration of		voted to approve
		Vaccinations, Epinephrine, and Diphenhydramine		motion
		SB 845 Hlth Occs - Pharm - Admin of Vacc, Epine, Diphen CROSS		
		<u>sb0845e</u>		
		The Maryland Board of Pharmacy Supports SB 845 Health Occupations –		
		Pharmacists – Administration of Vaccinations, Epinephrine, and		
		Diphenhydramine, as amended in the Senate.		
		During the 2009/2010 H1N1 flu season, the Secretary of the Department of		

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		Health and Mental Hygiene (DHMH) issued an Executive Order authorizing licensed, certified pharmacists to administer the H1N1 vaccine to individuals 13 years old and older. This Executive Order was in effect from December 11, 2009 through February 7, 2010. During this time pharmacists were able to administer vaccines to parents and their children 13 years old and older. The results were positive and no adverse reactions or injuries were reported. This Executive Order made it possible for many more individuals to be vaccinated with the H1N1 vaccine.	, <u> </u>	
		The Board supports lowering the age to at least 7 years old so that entire families may be vaccinated at one time. This would be a great convenience and incentive for families to obtain vaccinations. Other states have lowered the age for pharmacist administration of vaccinations to children and the results have been positive.		
		The Board asks for a favorable report for SB 845 Health Occupations – Pharmacists – Administration of Vaccinations, Epinephrine, and Diphenhydramine as amended in the Senate.		
		b. SB 770/HB 460 Prescription Drug Repository Program – Disposal of Prescription Drugs and Medical Supplies		
		SB 770 RxDrugRepProg-Disposal of RxDrugs&Med Supplies CROSS		
		<u>sb0770t</u>		
		The Maryland Board of Pharmacy Supports SB 770 Prescription Drug Repository Program - Disposal of Prescription Drugs and Medical Supplies, as amended by the Senate. The Board initiated this legislation to provide accountability for disposing pharmacies; to prevent potential hazards to children and young adults; to protect the environment; and to compliment recently strengthened federal requirements under the Secure and Responsible Drug Disposal Act of 2010. The application process is simple and there is no fee to apply.		
		More and more pharmacies are participating in programs such as "DisposeMyMeds" and "Take Away." These programs lack accountability for what is donated for disposal. Expansion of the Prescription Drug Repository Program to include disposal would provide accountability and increase awareness of the original purpose of the program. Some pharmacies proactively collect unwanted, unused or expired prescription medications		

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	through various disposal programs, which accommodate customers while also protecting the environment. The Board is concerned that the true outcome of drugs returned to pharmacies is not known and Maryland law does not specifically address record keeping requirements for the receipt or returned unwanted or expired medications for disposal. Thus, the Board believes that the increase in the number of Maryland pharmacies that receive returned medications and the potential harm to the environment if they are not properly disposed, warrants greater State regulatory oversight. Required enrollment in this program would assure proper handling and accountability for donated and returned prescription drugs and devices; may provide support to customers who may otherwise be unable to pay for certain medications; and further supports the pharmacies efforts to dispose of medications. The Board is aware of the compelling public safety and environmental issues relating to the disposal of unwanted medications. Many consumers have numerous unused or outdated prescriptions in their homes. Many family members are left with a bounty of unused prescription medications when loved ones die. The Board is also cognizant of the serious potential hazards to children and teenagers who may pull discarded medications from the trash, or medicine cabinets and ingest them. Expanding the purpose of the repository program would also compliment the recently signed federal legislation to amend the Controlled Substances Act to provide for take-back disposal of controlled substances in certain instances. The Board would address disposal in a separate regulation within the COMAR chapter 10.34.33, once the federal regulations have been promulgated. Additionally, the Board would address in regulations any medications that are required by federal law to meet special handling requirements or may have specific restrictions under the U.S. Food and Drug Administration. Since this legislation was introduced the Board worked with the Attorney General's Offic		
	Therefore, the Board accepts and supports the one amendment passed by the Senate Education, Health and Environmental Affairs Committee for SB 770.		

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		The Board asks for a favorable report for SB 770 Prescription Drug Repository Program - Disposal of Prescription Drugs and Medical Supplies.		
		c. HB 1338/SB 974 Health Insurance – Pharmacy Benefit Managers – Contracts, Disclosures, and Audits		
		SB 974 Hlth Ins-PBM-K,discloures,audits 031611		
		<u>sb0974t</u>		
		The Maryland Board of Pharmacy (the "Board") submits this Letter of Support regarding SB 974 Health Insurance – Pharmacy Benefits Managers – Contracts, Disclosures, and Audits.		
		SB 974 requires that each contract between a pharmacy benefits manager (PBM) and a pharmacy, pharmacist, or retail pharmacy network contain at a minimum certain provisions. A provision added for this legislation would require the PBM to use the most current nationally recognized reference price in the actual or constructive possession of the PBM, if a PBM calculates reimbursement for prescription drugs and other products in accordance with a formula that uses a nationally recognized reference in the pricing calculation. Additionally, a PBM that has a management or ownership interest in a pharmacy, pharmacist, or retail pharmacy network or is the agent of a pharmacy, pharmacist, or retail pharmacy network may not discriminate or restrict the rights of a beneficiary or offer preferential copayments to a beneficiary based on a pharmacy classification of trade. The bill sets forth a few additional requirements for a PBM when performing an audit that include auditing the same number of chain pharmacies and independent pharmacies and auditing the same number of brand and generic prescription drugs. The legislation includes a recoupment of a claims payment from a pharmacy or pharmacist by a PBM based only on the actual dispensing fee and may not include the cost of the prescribed drug dispensed. Finally, clerical errors may not be a basis for denial of a claim, imposition of a penalty, or recoupment from a pharmacy, pharmacist or retail pharmacy network.		
		The Board supports this legislation because it appears to embrace fairness in auditing, and fairness in payment, to pharmacists,		

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		pharmacies and retail pharmacy networks. The bill appears to reduce discriminatory pricing by PBMs. In the past pharmacists and pharmacies have had a difficult time receiving payment from PBMs based on minor clerical errors. The Board supports a remedy to this situation.		
		Therefore, the Board requests a favorable report on SB 974.		
		3. MOLST Meetings		
		Report on the March 30, 2011 meeting		
		Anna Jeffers reported that the March 30, 2011 Meeting for the Medical Orders for Life Sustaining Treatment (MOLST) forms was held to assist long term care stakeholders and long term care facility owners and operators in preparing educational materials to train their personnel regarding how to complete and implement the MOLST forms. Pharmacy stakeholders would not participate in this aspect of the training process.		
		4. DHMH Task Force on Regulatory Efficiency		
		A kick-off meeting was held by DHMH in the House Health and Government Operations Committee Hearing Room in Annapolis on April 4, 2011 to establish a Task Force to simplify health care facility regulations. The purpose of the meeting was to solicit comment from stakeholders regarding how to revise health care facility regulations so that the regulations are more efficient and less duplicative. The review will cover regulations of all facilities licensed by DHMH, including skilled nursing facilities, assisted living facilities, community programs for individuals with mental health, substance use concerns, hospice, hospitals, programs for individual with developmental disabilities, laboratories, adult day care and in—home services.		
		5. National Take Back Day is April 30, 2011.6. MedChi Final Report, April 11, 2011 Mike Souranis quoted a section of the report that indicated that "the Department worked in concert with the physician community to defeat		
		the balance of the legislative proposals." He had concerns that the Department had been working with the physicians and asked Anna		

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	Jeffers if she knew what the Department's position had been on legislation during the Session. Kristen Neville, Legislation and Regulations Liaison for most of the Health Occupation Boards, explained that the Legislative Liaisons are not made aware of the Department's position at the Friday morning meetings. The Department's positions are determined later that day and submitted to the Governor's Office for approval over the weekend. Senator Hollinger added that the MedChi report may have been exaggerated by the lobbyist Jay Schwartz, who wrote the report. Mike Souranis asked that a letter be written to the Secretary to make him aware of the content of the MedChi report. 3. Letters for Board Approval a. Seema Kanwar, Waller Lansden Dortch & Davis Question re automated medication systems DRAFT - Bd Response - automated medication systems DonMitra Thank you for contacting the Maryland Board of Pharmacy concerning whether an entity may provide an automated emergency drug kit to a comprehensive care facility. Additionally you asked if such an automated medication system may be restocked by a nurse. Finally, you asked what constitutes "sufficient safeguards" in COMAR 10.34.28.06B. An entity may only provide an automated emergency drug kit to a comprehensive care facility if it is the pharmacy servicing that facility. Please be advised to refer to the Maryland Board of Nursing to		
	determine if nurses may replenish automated medication systems. In the existing regulations, 10.34.28.06B(2), automated medication systems that possess sufficient safeguards to ensure accuracy of the replenishment may be filled by health care professionals licensed under Health Occupations Article, Annotated Code of Maryland, and permitted access to an automated medication system due to the health care professionals' privileges to administer medication.		
	A. H. Finke, Chair, Practice	Jeffers if she knew what the Department's position had been on legislation during the Session. Kristen Neville, Legislation and Regulations Liaison for most of the Health Occupation Boards, explained that the Legislative Liaisons are not made aware of the Department's position at the Friday morning meetings. The Department's positions are determined later that day and submitted to the Governor's Office for approval over the weekend. Senator Hollinger added that the MedChi report may have been exaggerated by the lobbyist Jay Schwartz, who wrote the report. Mike Souranis asked that a letter be written to the Secretary to make him aware of the content of the MedChi report. 3. Letters for Board Approval A. H. Finke, Chair, Practice Committee. DRAFT - Bd Response - automated medication systems DRAFT - Bd Response - automated medication systems DonMitra Thank you for contacting the Maryland Board of Pharmacy concerning whether an entity may provide an automated emergency drug kit to a comprehensive care facility. Additionally you asked if such an automated medication system may be restocked by a nurse. Finally, you asked what constitutes "sufficient safeguards" in COMAR 10.34.28.06B. An entity may only provide an automated emergency drug kit to a comprehensive care facility if it is the pharmacy servicing that facility. Please be advised to refer to the Maryland Board of Nursing to determine if nurses may replenish automated medication systems. In the existing regulations, 10.34.28.06B(2), automated medication systems that possess sufficient safeguards to ensure accuracy of the replenishment may be filled by health care professionals licensed under Health Occupations Article, Annotated Code of Maryland, and permitted access to an automated medication system due to the	Jeffers if she knew what the Department's position had been on legislation during the Session. Kristen Neville, Legislation and Regulations Liaison for most of the Health Occupation Boards, explained that the Legislative Liaisons are not made aware of the Department's position at the Friday morning meetings. The Department's position at the Friday morning meetings. The Department's position are determined later that day and submitted to the Governor's Office for approval over the weekend. Senator Hollinger added that the MedChi report may have been exaggerated by the lobbyist Jay Schwartz, who wrote the report. Mike Souranis asked that a letter be written to the Secretary to make him aware of the content of the MedChi report. 3. Letters for Board Approval A. H. Finke, Chair, Practice Committee. DRAFT - Bd Response - automated medication systems DRAFT - Bd Response - automated medication systems DRAFT and Response - automated medication systems DRAFT - Bd Response - automated medication systems bonMitra Thank you for contacting the Maryland Board of Pharmacy concerning whether an entity may provide an automated emergency drug kit to a comprehensive care facility. Additionally you asked if such an automated medication system may be restocked by a nurse. Finally, you asked what constitutes "sufficient safeguards" in COMAR 10.34.28.06B. An entity may only provide an automated emergency drug kit to a comprehensive care facility if it is the pharmacy servicing that facility. Please be advised to refer to the Maryland Board of Nursing to determine if nurses may replenish automated medication systems. In the existing regulations, 10.34.28.06B(2), automated medication systems. In the existing regulations, 10.34.28.06B(2), automated medication systems and permitted access to an automated medication system due to the

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Subject		This spring new regulations will be proposed regarding automated medication systems. What constitutes "sufficient safeguards" in COMAR 10.34.28.06B could be bar coding or another tracking method to ensure that the right drug is dispensed to the right patient at the right time. b. Darlene Fleishman, Medchi Generic vs. Brand (cost) DRAFT - Bd Response - Generic vs. Brand DonMitra Thank you for contacting the Maryland Board of Pharmacy concerning how a generic prescription could be filled for more than the cost of a brand name medication even though Health Occupations Article, 12-504, Annotated Code of Maryland, indicates that a pharmacist may substitute a generically equivalent drug of the same dosage form and strength, for any brand name drug if the consumer is charged less for the substituted drug or device than the price of the brand name drug. Generic formulations may be manufactured for any brand name product no		
		longer on patent. Generic pricing is usually much cheaper than the branded name product, but could, in rare instances, actually be more than the brand name due to rebates and special pricing available for the brand name drug. Your inquiry appears to be an insurance or payment issue. Most insurance providers have established a tiered payment schedule for various medications. It is also possible that a new generic product may initially be placed into a different tier than the brand product because there is a 6 month exclusivity for the generic manufacturer for a new generic drug. This may also result in the insurance provider charging the patient more for the generic product than for the brand name product. C. Christopher Dang, Carpenter Law Firm Maryland Pharmacy Delivery and Drop-Off Questions DRAFT - Bd Response - Delivery and Drop off	3c-Motion: Practice Committee to amend question #6 Seconded: D. Chason	

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		Thank you for contacting the Maryland Board of Pharmacy concerning the practice of pharmacy in Maryland with regards to in-state pharmacy deliveries, prescription drop-off, and prescription "depoting." Below you will find responses to your inquiries:	·	3c-Board Action: The Board voted to approve motion
		May a licensed local retail pharmacy deliver filled prescriptions directly to patients at their place of employment?		
		Yes, you may deliver directly to the patient at their place of employment, and not to a depot as defined in COMAR 10.34.25.02 and 04, so long as you comply with all HIPAA and delivery standards.		
		2. May the prescription be delivered to the patient's place of employment, but left with a patients receptionist or with the mail room?		
		No, prescriptions may not be delivered to a "depot" as defined in COMAR 10.34.25.02 and .04.		
		3. May a locally licensed pharmacy deliver a filled prescription to a clinic that issued the prescription located at the patient's place of employment? If that is permissible, may a pharmacy also deliver filled prescriptions to that clinic if the prescription was written by a non-clinic prescriber for the patient to pick up?		
		Yes, a locally licensed pharmacy may deliver a filled prescription to a clinic that issued the prescription located at the patient's place of employment if the clinic is a licensed health care facility or a prescriber's office. See COMAR 10.34.25.02B(2)(b)(i) and (ii) and 10.34.25.04		
		Additionally, a pharmacy may also deliver filled prescriptions to that clinic if the prescription was written by a non-clinic prescriber for the patient to pick up.		
		4. May a new prescription order be dropped off at somewhere other than the pharmacy? (e.g., a drop box at the place of employment or a clinic?)		
		No, this leaves open the possibility of HIPAA violations as well as the possibility that the prescription may never reach the pharmacy.		
		5. May one retail pharmacy act as a place for prescription drop off (prescription depot) for another store? (e.g., may a patient drop of a		

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		prescription at a local pharmacy for filling and delivery by a specialty pharmacy?)		
		Yes, in the prescription area only. See COMAR 10.34.25.02B(2)(b)(iii) and 10.34.25.04		
		6. May a specialty pharmacy (typically out of state) deliver a filled prescription to a local retail pharmacy for customer pick up? (e.g., may a local retail pharmacy act as a filled prescription depot)		
		Yes, but in the prescription area only as this is not a depot as defined by Maryland law. See COMAR 10.34.25.02B(2)(b)(iii) and 10.34.25.04		
		d. Charles Sandler, Md Medicaid	3d- Motion: Practice	
		<u>Dispensing physicians – administering</u>	Committee	
		DRAFT - Bd Response - physicians administering	Seconded: D. Taylor	
		Thank you for contacting the Maryland Board of Pharmacy concerning whether a physician is "dispensing" or "administering" when the physician purchases prescription medications from a wholesale distributor, pharmacy, or manufacturer and then administers the medications to the physician's patients in the physician's office.		Board Action: The Board voted to approve motion
		Please be advised when a physician purchases prescription medications from a wholesale distributor, pharmacy, or manufacturer and then administers the medication to the physician's patients in the physician's office, it is considered "administering."		
		e. Gil Cohen		
		SB 291 2010 - posting of final orders inquiry	3e- Motion: Practice Committee	
		DRAFT - Bd Response - posting of final orders Don	Seconded: R. Matens	
		Thank you for contacting the Maryland Board of Pharmacy concerning posting on the Board website "each final, public order for a disciplinary sanction issued to a licensee" pursuant to the 2010 Senate Bill 291 – Health		Board Action: The Board voted to

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		Occupations – Revisions. Since no timeframe was established in SB 291 for posting public orders, you maintained that an uncodified Section 5 at the end of the SB 291 would apply. That section states: "That, except as otherwise provided by law, this Act shall be construed to apply only prospectively and may not be applied or interpreted to have any effect on or application to any complaint made to a health occupations board before the effective date of this Act." The Board, as well as the other Health Occupation Boards, respectfully disagrees with your interpretation that only public orders issued after the effective date of the bill would be posted on the Board's website. The legislative mandate for posting public orders was to give the public notice of all public orders filed against their health care providers. The Health Occupation Boards, in trying to fulfill that mandate, believe that the intent of the Legislature was to provide the public with all pertinent information about their health care providers, or potential health care providers, to allow patients to make informed choices. From a public policy perspective, not posting all existing public orders would not give the public accurate information about the health care professionals they use or might wish to use in the future. One of the mandates of SB 291 was a study to be performed by the Health Occupation Boards and the Department of Health and Mental Hygiene which would examine whether it would be appropriate to expunge disciplinary proceedings from a licensee's file after a specified period of time and then to report those findings to the Senate Education, Health, and Environmental Affairs Committee and the House Health and Government Operations Committee. That report was timely filed and you may obtain a copy by contacting your legislator.		approve motion
		f. Susan Pierce, Target MD Pharmacy Physical Requirements Question	3f- Motion: Practice Committee	
		DRAFT - Bd Response - computer monitors at pharm wrk statio Don	Seconded: D. Taylor	
		Thank you for contacting the Maryland Board of Pharmacy concerning whether installing a computer monitor at a pharmacy front counter, at the drop off window, to be used by pharmacy staff to check patients in, to ensure that the pharmacy has the appropriate patient information, and by pharmacists		3f-Board Action: The Board voted to approve motion

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		for reviewing a profile prior to counseling would comply with Maryland law and regulations. The workstation would be located at a drop off area that is not secured behind the pharmacy gate. However, the following protections would be implemented: (1) the CPU unit is secured in a locked cabinet or a cage, which requires a key to be opened; (2) no patient information is stored on the workstation, but rather in Target's central data base center; (3) access to the system is based on job code, and could only be used by pharmacists or technicians with a username and password; (4) the workstation automatically locks after 10 minutes; and (5) the best practice is to lock the screen anytime a pharmacy employee walks away from the workstation. Please be advised that as long as there is no customer, or non-pharmacy personnel, access to patient information on the computer monitor, it would comply with Maryland laws and regulations. There may be HIPAA concerns, however; because the workstation only automatically locks after 10 minutes. Ten minutes appears to be a long time for a monitor to be potentially unattended on a pharmacy counter. The Board would suggest that the monitor should be positioned so that customers and non-pharmacist personnel may not view any personal information that may be on the screen.		
	B. D. Chason, Chair, Licensing Committee.	 S. Cylus, daughter of a deceased pharmacist, E. Yevzeroff, requested a refund of \$251 fee paid by her mother upon renewing in October 2010. E. Yevzeroff mother passed away 1/2011. Milanich, Greg- Mr. Milanich requested a 60 day extension of his ATT authorization number from NABP to take the MPJE examination. NABP informed him that the extension approval should come from the Board. 	B1- Motion: Licensing Committee moved that that request be denied based on the fact that the payment was for administrative fees and not refundable. Seconded: R. Zimmer B2- Motion: Licensing Committee moved to make no decision on the request and referring him back to NABP since he may obtain an extension by paying NABP an extension fee. Seconded: D. Taylor	B1- Board Action: The Board voted to approve motion B2 -Board Action: The Board voted to approve motion

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		Advanced Medical Supplies- Submitted application after deadline and requested waiver.	B3- Motion: Licensing Committee move for an Administrative Denial because there is no VAWD accreditation.	B3-Board
		Clayton's Pharmacy- Submitted application to become a Prescription Drug Repository.	Seconded: D. Taylor B4- Motion: Licensing Committee Seconded: L. Israbian- Jamgochian	Action: The Board voted to approve motion
		Super Valu – Submitted pharmacy technician examination for approval (technician training program was previously approved.	B5-Motion; Licensing committee moved to approve the exam Seconded: R. Zimmer	B4-Board Action: The Board voted to approve motion
		Sanford Brown Institute Landover submitted Pharmacy Technician Examination for approval.	B 6- Motion: Licensing Committee moved to approve application. Seconded: M. Gavgani	B5-Board Action: The Board voted to approve motion
		7. R. Taylor reported that he has received applications for approval of CE for on-line program offered by Alleghany Community college. The programs are being offered for technicians to complete for renewal. R. Taylor presented the results of his review of the on line CE application. The request was for approval of 4 hours of CE.	B7- Motion: Licensing Committee moved to limit on-line CE program to 2 hours Seconded: H. Finke	B6-Board Action: The Board voted to approve motion
		 8. CJIS will not provide criminal background reports after six months from the date that an original report is provided. 9. The Committee members discussed the changes in the new legislation regarding Repositories. D. Chason to contact A. Jeffers to request a copy of the new legislation. 	B8- Motion: Licensing Committee moved is to limit use of CJIS reports to six months from the date of first issue, unless delays due to processing issues by the Board.	B7-Board Action: The Board voted to approve motion B8-Board Action: The

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			Seconded: H. Finke	Board voted to approve motion
			B9 Motion: Licensing Committee moved that a sub-committee be appointed to review the need for changes to the Prescription Repository regulations and inspection form based on the recent statutory changes. Seconded: L. Israbian- Jamgochian	B9- L. Israbian- Jamgocian, D. Taylor and D. Chason assigned to subcommittee to review the need for any changes
	C. L. Bradley- Baker, Chair, Public Relations Committee	L. Bradley-Baker reported that the spring 2011 newsletter is currently being developed. Janet Seeds is requesting that all articles be submitted by April 29, 2011. She is also working on the Annual Report. The Public Relations Committee is reviewing the website and continuing to determine come up with criteria for what should be posted on the site. The Board will be participating in the Annual Flower Mart on Friday May 6, 2011. Volunteers to greet consumers at the Board's booth. L. Bradley-Baker was asked to review the Maryland State Health Improvement Plan (SHIP). This plan will develop a framework to support improvements in all Marylanders' Health. SHIP looks at five vision areas, which are: 1. Improving reproductive health care and Birth Outcomes; 2. Ensuring that Maryland Indoor and Community Environments are Safe and support healthy living; 3. Preventing and Controlling of Infectious Diseases; 4. Preventing and Controlling of Chronic Diseases; 5. Ensuring that all Marylanders receive the health care need. L. Bradley-Baker recommended that the Board submit formal comments as follows: 1. Under Vision Area 3 (Prevent and Control Infectious Disease), objective 20 (increase the season influenza vaccine rates). It currently states that 42.1% of Maryland's populations are vaccinated yearly for seasonal influenza, with a target goal of 80% of the population. The Board would like to see health care provider vaccinations addressed (perhaps as a sub objective). Health care providers should be immunized yearly to assist in reducing the spread of influenza (the goal	Motion: Public Relations Committee recommend approve a response Seconded: D. Taylor	Board Action: The Board voted to approve motion

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	D. L.	for this population should be 100%); and 2. Noting that Improving health in Maryland will occur at a faster rate when all of the health care providers available to patients work together (i.e., similar to when medical home model) for the patient. There should be some reference to this within the plan perhaps, not as an objective, but part of the overall purpose or conditions necessary to facilitate the successful execution of the plan targets. Manner of Issuance of Prescriptions - COMAR 10.19.03.07.D		
	Israbian- Jamgochian, Chair Disciplinary Committee	Discussion of a inquiry of this regulation was received and members determined that in accordance with the FDA as long as required prescription information were contained on a sticky on the prescription it would be acceptable.		
	E. D. Taylor Emergency Preparedness Task Force	D. Taylor reported the following Task Force Updates: There will be a statewide drill on pandemic influenza on May 3, 2011. OPR has written Pharmacy into a section of the plan. Emergency Preparedness Committee will be responding to the RSS and part of the exercise. Our exact duties there have not been disclosed yet. Pharmacy will be representing some part of the plan at the RSS. This will be the first time Pharmacy has been written into the plan. D. Taylor received a letter from OPR and Secretary Sharfstein thanking the Board for our participating in the 2011 TAR and our Board continuing support. L. Naesea Congratulated D. Taylor and the Committee.		
IV. Other Business	A. M. Souranis			
	B. Drug Therapy Management	R. Taylor reported on the Drug Therapy Management meeting he attended on April 13, 2011. The Board of Pharmacy and the Board of Physicians continued working on some of the pending protocols. There are 11 pending protocols at this point that needs to be addressed by the MBP. There was some movement in the right direction. We are not sure how committed the Board of Physicians is to the idea of collaborative practice via DTM. The Board of Physicians still needs to review and vote on the old and new protocols. Both Boards did agree on the renewal of Finke's Pharmacy, but the Board of Physicians still needs to vote on the protocol.		

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	C. FYI			
V. Adjournment	M. Souranis, Board President	The Public Meeting was adjourned at 12:05 p.m. B. At 12:48 p.m. M. Souranis convened a Closed Public Session to conduct a medical review of technician applications.	Motion: R. Zimmer made a motion to close the Public Meeting. Seconded the motion: D. Chason	Board Action: The Board voted to approve the motion.
		C. The Closed Public Session was adjourned at 1:03 p.m. Immediately thereafter, M. Souranis convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session.		